



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL  
FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

7+

Application Number	10/630,074
Filing Date	07/30/2003
First Named Inventor	David R. Milich
Art Unit	1648
Examiner Name	Peng, B.
Attorney Docket Number	
VACCINE-07971	

Attorney Docket Number

VACCINE-07971

## ENCLOSURES (Check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input checked="" type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Form PTO-1449 & copies of 28 references cited therein
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Reply to Missing Parts/ Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		
Remarks		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Medlen & Carroll, LLP		
Signature			
Printed name	Christine A. Lekutis		
Date	May 10, 2006	Reg. No.	51,934

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Cliff Cannon-Cin	Date	May 10, 2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

Effective on 12/08/2004.

Pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL For FY 2005

Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** (\$)  
180.00

## Complete if Known

Application Number	10/630,074
Filing Date	07/30/2003
First Named Inventor	David R. Milich
Examiner Name	Peng, B.
Art Unit	1648
Attorney Docket No.	VACCINE-07971

## METHOD OF PAYMENT (check all that apply)

Check  Credit Card  Money Order  None  Other (please identify): \_\_\_\_\_

Deposit Account Deposit Account Number: 08-1290 Deposit Account Name: Medlen & Carroll, LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below  Charge fee(s) indicated below, except for the filing fee

Charge any additional fee(s) or underpayments of fee(s)  Credit any overpayments under 37 CFR 1.16 and 1.17

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

## FEE CALCULATION

### 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	_____
Design	200	100	100	50	130	65	_____
Plant	200	100	300	150	160	80	_____
Reissue	300	150	500	250	600	300	_____
Provisional	200	100	0	0	0	0	_____

### 2. EXCESS CLAIM FEES

#### Fee Description

Each claim over 20 (including Reissues)

Each independent claim over 3 (including Reissues)

Multiple dependent claims

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Small Entity	
				Fee (\$)	Fee (\$)
61	- 20 or HP = 0	x _____	= _____	50	25

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims	
				Fee (\$)	Fee Paid (\$)
4	- 3 or HP = 0	x _____	= _____	_____	_____

HP = highest number of independent claims paid for, if greater than 3.

### 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____	- 100 = _____	/ 50 = _____ (round up to a whole number)	x _____	= _____

### 4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Information Disclosure Statement fee

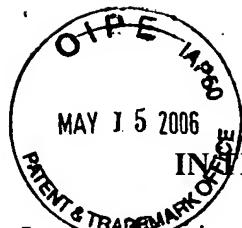
180

## SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 51,934	Telephone 415.904.6500
Name (Print/Type)	Christine A. Lekutis		Date May 10, 2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



**PATENT**  
Attorney Docket No. VACCINE-07971

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: David R. Milich *et al.*  
Serial No.: 10/630,074 Group No.: 1648  
Filed: 07/30/2003 Examiner: Peng, B.  
Entitled: **Human Hepatitis B Virus Core Proteins As Vaccine Platforms  
And Methods Of Use Thereof**

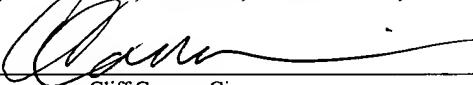
**SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT**

**MS Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 10, 2006.

By: 

Cliff Cannon-Cin

Dear Sir:

The citations listed below, copies of non-U.S. patents and published applications attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. § 1.56 and § 1.97. The Examiner is requested to make these citations of official record in this application:

- U.S. Patent No. 5,990,085 to Ireland *et al.*, "Inhibin-HBc fusion protein," (1999);
- U.S. Patent No. 6,887,464 to Coleman *et al.*, "Advanced antigen presentation platform," (2005);
- U.S. Publication No. US 2003/0099668 of Bachmann *et al.*, "Packaging of immunostimulatory substances into virus-like particles: method of preparation and use," (2003);
- U.S. Publication No. US 2004/0054139 of Page *et al.*, "Modification of hepatitis B core antigen," (2004);

05/16/2006 SSANDARA 00000018 10630074  
01 FC:1806 180.00 0P  
01 FC:1806 180.00 0P

05/16/2006 SSANDARA 00000018 10630074  
01 FC:1806 180.00 0P

- U.S. Publication No. US 2004/0146524 of Lyons *et al.*, “Stabilized immunogenic HBc chimer particles,” (2004);
- U.S. Publication No. US 2004/0152876 of Birkett, “Immunogenic HBc chimer particles having enhanced stability,” (2004);
- U.S. Publication No. US 2004/0156864 of Birkett, “Immunogenic HBc chimer particles having enhanced stability,” (2004);
- U.S. Publication No. US 20040219164 of Coleman *et al.*, “Advanced antigen presentation platform,” (2004);
- U.S. Publication No. US 2005/0208068 of Milich *et al.*, “Malaria immunogen and vaccine,” (2005);
- Japanese Patent Application Publication No. JP7252300 of Okamoto “Antigen fused protein from duck hepatitis virus and human hepatitis virus and its production,” (1995) in Japanese with English translation of abstract and specification;
- PCT Publication No. WO 95/27083 of Milich *et al.*, “Method for diagnosing chronic hepatitis B virus infection,” (1995);
- PCT Publication No. WO 99/40934 of Birkett, “Strategically modified hepatitis B core proteins and their derivatives,” (1999);
- PCT Publication No. WO 00/46365 of Coleman *et al.*, “Advanced antigen presentation platform,” (2000);
- Belnap *et al.*, “Diversity of core antigen epitopes of hepatitis B virus,” Proc Natl Acad Sci USA, 100:10884-10889 (2003);
- Fietelson *et al.*, “Core particles of hepatitis B virus and ground squirrel hepatitis virus,” J Virol, 43:687-696 (1982);
- Fietelson *et al.*, “Monoclonal antibodies raised to purified woodchuck hepatitis virus core antigen particles demonstrate X antigen reactivity,” Virology, 177:357-366 (1990);
- Galibert *et al.*, “Nucleotide sequence of a cloned woodchuck hepatitis virus genome: Comparison with the hepatitis B virus sequence,” J Virol, 41:51-65 (1982);
- Gallina *et al.*, “A recombinant hepatitis B core antigen polypeptide with the protamine-like domain deleted self-assembles into capsid particles but fails to bind nucleic acids,” J Virol, 63:4645-4652 (1989);

- Kidd-Ljunggren *et al.*, "Genetic variability in hepatitis B viruses," *J Gen Virol*, 83:1267-1280 (2002);
- Koschel *et al.*, "Extensive mutagenesis of the hepatitis B virus core gene and mapping of mutations that allow capsid formation," *J Virol*, 73:2153-2160 (1999);
- Marion *et al.*, "A virus in Beechey ground squirrels that is related to hepatitis B virus of humans," *Proc Natl Acad Sci USA*, 77:241-2945 (1980);
- Mason *et al.*, "Virus of Pekin ducks with structural and biological relatedness to human hepatitis B virus," *J Virol*, 36:829-836 (1980);
- Milich *et al.*, "Immune response to hepatitis B virus core antigen (HBcAg): Localization of T cell recognition site within HBcAg/HBeAg," *J Immunol*, 139:1223-1231 (1987);
- Milich *et al.*, "Antibody production to the nucleocapsid and envelope of the hepatitis B virus primed by a single synthetic T cell site," *Nature*, 329:547-549 (1987);
- Milich *et al.*, "Comparative immunogenicity of hepatitis B virus core and E antigens" *J Immunol*, 141:3617-3624 (1988);
- Millman *et al.*, "Immunological Cross-reactivities of woodchuck and hepatitis B viral antigens," *Infect Immun*, 35:752-757 (1982);
- Ponzetto *et al.*, "Core antigen and antibody in woodchucks after infection with woodchuck hepatitis virus," *J Virol*, 52:70-76 (1984);
- Ponzetto *et al.*, "Radioimmunoassay and characterization of woodchuck hepatitis virus core antigen and antibody," *Virus Res*, 2:301-315 (1985);
- Pumpens and Grens, "Hepatitis B core particles as a universal display model: A structure-function basis for development," *FEBS Letters*, 442:1-6 (1999);
- Schodel *et al.*, "Immunization with recombinant woodchuck hepatitis virus nucleocapsid antigen or hepatitis B virus nucleocapsid antigen protects woodchucks from woodchuck hepatitis virus infection," *Vaccine*, 11:624-628 (1993);
- Shanmuganathan *et al.*, "Mapping of the cellular immune responses to woodchuck hepatitis core antigen epitopes in chronically infected woodchucks," *J Med Virol*, 52:128-135 (1997);

- Stannard *et al.*, "Antigenic cross-reactions between woodchuck hepatitis virus and human hepatitis B virus shown by immune electron microscopy," *J Gen Virol*, 64:975-980 (1983);
- Tarar *et al.*, "Expression of a human cytomegalovirus gp58 antigenic domain fused to the hepatitis B virus nucleocapsid protein," *FEMS Immunol Med Microbiol*, 16:183-192 (1996);
- Ulrich *et al.*, "Core particles of hepatitis B virus as carrier for foreign epitopes," *Advances in Virus Research*, 50:141-182 (1998);
- Werner *et al.*, "Serological relationship of woodchuck hepatitis virus to human hepatitis B virus," *J Virol*, 32:314-322 (1979);
- Zheng *et al.*, "The structure of hepadnaviral core antigens," *J Biol Chem*, 267:9422-9429 (1992); and
- Zlotnick *et al.*, "Localization of the C terminus of the assembly domain of hepatitis B virus capsid protein: Implications for morphogenesis and organization of encapsidated RNA," *Proc Natl Acad Sci USA*, 94:9556-9561 (1997).

This Information Disclosure Statement under 37 C.F.R. § 1.56 and § 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: May 10, 2006



Christine A. Lekutis  
Registration No. 51,934

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
415/904-6500

FORM PTO-1449  
(Modified)U.S. Department of Commerce  
Patent and Trademark Office

Attorney Docket No.: VAGCINE-07971

Serial No.: 10/630,074

INFORMATION DISCLOSURE STATEMENT BY APPLICANT  
(Use Several Sheets If Necessary)  
(37 CFR § 1.98(b))Applicant: David R. Milich *et al.*

Filing or 371(c) Date: 07/30/2003

Group Art Unit: 1648

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	5,990,085	11/23/1999	Ireland <i>et al.</i>			
	2	6,887,464	05/03/2005	Coleman <i>et al.</i>			
	3	2003/0099668	05/29/2003	Bachmann <i>et al.</i>			
	4	2004/0054139	03/18/2004	Page <i>et al.</i>			
	5	2004/0146524	07/29/2004	Lyons <i>et al.</i>			
	6	2004/0152876	08/05/2004	Birkett			
	7	2004/0156864	08/12/2004	Birkett			
	8	2004/0219164	11/04/2004	Coleman <i>et al.</i>			



## FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	9	JP7252300	10/03/1995	Japan			X	
	10	WO 95/27083	10/12/1995	WIPO				
	11	WO 99/40934	08/19/1999	WIPO				
	12	WO 00/46365	08/10/2000	WIPO				

## OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	13	Belnap <i>et al.</i> , "Diversity of core antigen epitopes of hepatitis B virus," Proc Natl Acad Sci USA, 100:10884-10889 (2003)
	14	Fietelson <i>et al.</i> , "Core particles of hepatitis B virus and ground squirrel hepatitis virus," J Virol, 43:687-696 (1982)
	15	Fietelson <i>et al.</i> , "Monoclonal antibodies raised to purified woodchuck hepatitis virus core antigen particles demonstrate X antigen reactivity," Virology, 177:357-366 (1990)
	16	Galibert <i>et al.</i> , "Nucleotide sequence of a cloned woodchuck hepatitis virus genome: Comparison with the hepatitis B virus sequence," J Virol, 41:51-65 (1982)
	17	Gallina <i>et al.</i> , "A recombinant hepatitis B core antigen polypeptide with the protamine-like domain deleted self-assembles into capsid particles but fails to bind nucleic acids," J Virol, 63:4645-4652 (1989)
	18	Kidd-Ljunggren <i>et al.</i> , "Genetic variability in hepatitis B viruses," J Gen Virol, 83:1267-1280 (2002)
	19	Koschel <i>et al.</i> , "Extensive mutagenesis of the hepatitis B virus core gene and mapping of mutations that allow capsid formation," J Virol, 73:2153-2160 (1999)
	20	Marion <i>et al.</i> , "A virus in Beechey ground squirrels that is related to hepatitis B virus of humans," Proc Natl Acad Sci USA, 77:241-245 (1980)
	21	Mason <i>et al.</i> , "Virus of Pekin ducks with structural and biological relatedness to human hepatitis B virus," J Virol, 36:829-836 (1980)
	22	Milich <i>et al.</i> , "Immune response to hepatitis B virus core antigen (HBcAg): Localization of T cell recognition site within HBcAg/HBeAg," J Immunol, 139:1223-1231 (1987)
	23	Milich <i>et al.</i> , "Antibody production to the nucleocapsid and envelope of the hepatitis B virus primed by a single synthetic T cell site," Nature, 329:547-549 (1987)
	24	Milich <i>et al.</i> , "Comparative immunogenicity of hepatitis B virus core and E antigens" J Immunol, 141:3617-3624 (1988)
	25	Millman <i>et al.</i> , "Immunological Cross-reactivities of woodchuck and hepatitis B viral antigens," Infect Immun, 35:752-757 (1982)

Examiner:

Date Considered:

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

